

**GASTROENTEROLOGY AND UROLOGY DEVICES PANEL
OF THE
MEDICAL DEVICES ADVISORY COMMITTEE**

June 8, 2005

Panel Chair:
Mark Talamini, M.D.
Professor of Medicine
Johns Hopkins School of Medicine
Baltimore, MD

Location: Gaithersburg Holiday Inn, 2 Montgomery Village Avenue, Gaithersburg, Maryland

NOTE: *Two ten-minute breaks and a one-hour lunch break will be determined at the discretion of the panel chair*

<u>CALL TO ORDER:</u>	9:00 a.m.
Agency's Critical Path Initiatives	9:00 to 9:15 a.m.
OSB Post Market Studies	9:15 to 9:30 a.m.
<u>OPEN PUBLIC HEARING*</u>	9:30 to 10:00 a.m.

Public attendees will be given an opportunity to address the Panel to present data or their views on the Panel's activities.

OPEN COMMITTEE DISCUSSION

1. Regulatory briefing – Carolyn Neuland, Ph.D.	10:00 to 10:15 a.m.
2. Overview of Conventional Hemodialysis Systems – Josh Nipper, M.E.	10:15 to 10:30 a.m.
3. Human Factors – Mike Mendelson, D.D.S., M.S. Biomed Eng	10:30 to 10:45 a.m.
4. FDA Presentation - Claudia Ruiz, M.D. Nephrologist	10:45 to 11:15 a.m.
5. Questions for the Panel	11:15 a.m.
Proposed lunch – 1 hour	12:30 p.m.
6. Continued: Questions for the Panel	1:30 p.m.

<u>OPEN PUBLIC HEARING*</u>	4:30p.m.
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Public attendees will be given an opportunity to address issues specific to the matter before the committee.

7. Final Comments	4:50 p.m.
8. Adjournment	5:00 p.m.

***OPEN PUBLIC HEARING**

Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee.

After the scheduled public speakers have spoken, the Chair may ask them to remain if the committee wishes to question them further. Dr. Talamini will recognize unscheduled speakers as time allows.

Note: Only the Chair and members of the Panel may question speakers during the open public hearing.

2005-414HAI AGENDA